

EXHIBIT B

IN THE UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: ETHICON INC., PELVIC) Master File No.

REPAIR SYSTEM PRODUCTS) MDL No. 2327

LIABILITY LITIGATION) JOSEPH R. GOODWIN

U.S. DISTRICT JUDGE

16 VIDEOTAPED DEPOSITION OF BRUCE S. KAHN, M.D.
17 SAN DIEGO, CALIFORNIA
18 THURSDAY, AUGUST 1, 2019
19 11:04 A.M.

1 Q It was your --

2 A Around 200 is what -- so --

3 Q Roughly about the first 200 of those
4 2,000?

5 A Yes.

6 Q If that math checks out.

7 A That math checks.

8 Q Doctor, can you explain to the jury --
9 we'll come back to that.

10 All right. Doctor, so about 2000, 2004,
11 '05, the Gynecare TVT is the product -- your product
12 of choice in your practice for SUI.

13 A Right, two -- no, that's not correct. So
14 around 2000 when I started using it, 2000 until 2004,
15 2005.

16 Q Right. So I apologize if I said that
17 wrong. From around 2002, 2004 or '05, your go-to
18 product for treatment of SUI was the Gynecare TVT.

19 A That is correct.

20 Q And roughly since that time, your main
21 product that you have implanted is the Boston
22 Scientific.

23 A That's correct.

24 Q Do you know what the product name is?

1 reduce the potential oxidative reaction with
2 ultraviolet light.

3 Santonox, S-A-N-T-O-N-O-X, 0.1 to 0.3
4 percent. An anticoagulant to promote stability
5 during compounding and extrusion.

6 Procol, P-R-O-C-O-L, LA-10, 0.25 to 0.35
7 percent. A lubricant to help reduce tissue drag and
8 promote tissue passage.

9 Last is CPC pigment, 0.55 percent max, a
10 colorant to enhance visibility.

11 BY MR. CLINTON:

12 Q And when was it that you learned about
13 the additives that you just explained, Doctor?

14 A Not until preparation for this case.

15 Q And, I apologize, you said that was --

16 A These cases.

17 Q -- about a year ago when you were
18 approached or a year and a half?

19 A A year and a half ago.

20 Q Before you were approached, Doctor, about
21 a year and a half ago, you had not implanted the TVT
22 in about a 15-year period, is that right, 14, 15
23 years?

24 MR. KOOPMANN: Object to form.

1 Go ahead.

2 THE WITNESS: Closer to ten years. 2004,
3 2014 -- yeah, 15 years. Okay. I'm sorry.

4 BY MR. CLINTON:

5 Q Yeah, I'm going to ask --

6 A Time flies.

7 Q Doctor, am I correct that you -- with the
8 exception of a little overlap in time when the
9 transition occurred, that you have not implanted a
10 TVT product in -- in the last ten years?

11 A Yeah, there was a TVT secure product that
12 I had some experience with. I'm not sure exactly
13 when that happened.

14 Q But the TVT retropubic that your report
15 is on, you have not implanted one of those in at
16 least ten years?

17 A That's correct.

18 Q And possibly up to 13, 14, 15 years?

19 A That's correct.

20 Q Did you keep up with literature about the
21 TVT product after the time you stopped utilizing it
22 in your practice?

23 A Yes. In the sense that I continued to
24 read about the treatment of stress urinary

1 receiving any payment from Boston Scientific.

2 It's -- I'm excited about the research I do, so I
3 will often talk about research I'm doing.

4 But actually that research on their sling
5 is -- it's completed and we're just writing it up at
6 this point. So it's not -- the work I'm doing now is
7 simply writing, and, you know, so -- does that answer
8 your question?

9 Q I'm not sure.

10 A You want to try it again?

11 Q Not really. Your --

12 A I'm trying.

13 Q Are you?

14 A I don't quite get it, you know.

15 Q So, Doctor, the research that you did --
16 so the reliance list, we talked about the documents
17 you had, documents that were provided to you, and
18 documents that you went and found on your own.
19 Literature research, things like that. That's fair?

20 A (The witness nods.)

21 Q What did you do to perform your own
22 research?

23 A Starting with internet-based searches,
24 looking for whatever topic I'm trying to look at

1 with -- you know, in the realm of TVTs, whether it be
2 complications or -- I honestly had to learn a lot
3 about -- in reviewing some of the plaintiffs' expert
4 reports, a lot of that information was new
5 information, and I wanted to go out and see if there
6 was anything, you know, to these things about
7 degradation and fraying.

8 And, you know, this was all kind of
9 things that I hadn't really heard much about in the
10 past, and I hadn't had any clinical problems
11 regarding them. So I did spend a fair amount of time
12 seeing -- searching out to see what there was that I
13 could find, you know, anything out there that I'm
14 kind of missing. That would be a good example of
15 something. So mostly internet searches. And then
16 when I would -- you know, go find -- look for the
17 article and see if there was anything there.

18 But I -- I can't remember any specifics
19 for you, but that's the basic mechanism. It was
20 basically using an internet search.

21 Q You mentioned a few topics that you --
22 that were somewhat new to you in reading the
23 plaintiffs' expert reports, and you identified
24 degradation and fraying. Is that right?

1 A Correct.

2 Q Are there other subjects that you -- that
3 were somewhat new to you that you had to go and dive
4 into research?

5 A I'm blanking on some of the terms they
6 used at this point, but there were several terms that
7 have been thrown around.

8 Q Roping and curling?

9 A That sounds familiar.

10 Q In your research about these subjects,
11 such as degradation, fraying, would you ask Ethicon
12 to -- to provide you internal documents about these
13 subjects?

14 A They were provided to me, and I didn't
15 ask them for additional stuff, but I reviewed a lot
16 of internal documents related to that.

17 Q They were provided to you?

18 A Correct.

19 Q Did you ask about what type of
20 information was being provided to you?

21 A I don't understand your question.

22 Q So documents were being provided to you
23 about these subjects. Were you asking -- did you
24 ever ask, Do I have everything on this?

1 going to have impact -- reasonably associated impact.

2 Okay?

3 So if someone had a concern about
4 fraying, I understand that, and I read through a lot
5 of that material. But when it comes to clinical
6 care, there -- the literature doesn't show there's
7 any -- anything to it. From my perspective, in my
8 opinion, I don't think that the -- that whole fraying
9 argument, there's just nothing to it when it comes to
10 clinical -- clinical application.

11 BY MR. CLINTON:

12 Q Have you ever done any studies on the
13 fraying of mesh or polypropylene, Doctor?

14 A I guess you could say I've done a pretty
15 good study for 20, 25 years with my own patients, and
16 I have not found that to be a problem.

17 MR. CLINTON: Object to form.

18 BY MR. CLINTON:

19 Q Doctor, have you ever conducted a study
20 specifically geared at looking at fraying of mesh or
21 polypropylene?

22 MR. KOOPMANN: Object to form.

23 THE WITNESS: I have not.

24 BY MR. CLINTON:

1 Q Doctor, have you ever --

2 A But again, I want to go back to adding
3 that, you know, it's something that I've paid
4 attention to in my clinical care of patients, and it
5 just hasn't been an issue.

6 Q Were you looking for fraying in the mesh
7 in 2000 when you began using the TVT product?

8 A I was looking for how my patients were
9 doing and to seeing if there were problems.

10 MR. CLINTON: I'm going to object to
11 form -- I mean, I object as nonresponsive.

12 MR. KOOPMANN: Hold on. Let him answer
13 the question, and then move to strike if you want to
14 move to strike and object as nonresponsive.

15 BY MR. CLINTON:

16 Q You may continue, Doctor.

17 MR. KOOPMANN: Thank you.

18 BY MR. CLINTON:

19 Q We're getting into that area where I'm
20 asking questions and you're giving answers about
21 something -- something else. So -- and I appreciate
22 you want to give a full and accurate answer.

23 Were you looking for fraying of the TVT
24 product when you began implanting it in 2000?

1 biocompatibility. What research have you done
2 regarding the biocompatibility of the TVT product?

3 Strike that.

4 When did your research begin about the
5 biocompatibility of the TVT product?

6 A Probably about the time I started
7 performing the TVT procedure back around 2000.

8 Q And when you say that, are you
9 referencing your clinical experience?

10 A Right. Clinical experience and -- and
11 research and -- and attendance at meetings and, you
12 know, are we having problems with this implant in
13 patients. So --

14 Q Do you have any --

15 A -- it goes back to the breadth and depth
16 of my -- you know, my clinical activity in general
17 going way back when. So...

18 Q Other than clinical experience in
19 implanting the mesh and monitoring patients who have
20 it implanted, do you have any training in the
21 biocompatibility of products implanted in the body?

22 A Sure. It really goes back to my -- my
23 experience, you know, as a physician, becoming a
24 physician. While I don't do research on, you know,

1 the polymers, I -- I do research with patients. I
2 take care of patients, clinical taking care of
3 patients. And so you have to understand it really
4 goes hand in hand. If you don't have an
5 understanding of biocompatibility of something you're
6 putting in a patient, if you're not following them
7 clinically, then it -- you wouldn't be performing
8 your duties as a physician well.

9 Q So is your opinion about the
10 biocompatibility of TVT solely based on your
11 experience as a clinician?

12 MR. KOOPMANN: Object to form.

13 THE WITNESS: No. Because in addition to
14 that, in developing my opinion here, I've been
15 provided a lot of additional information to -- and
16 found additional information on my own to develop the
17 opinions I've provided here.

18 BY MR. CLINTON:

19 Q Have you ever performed your own research
20 on the biocompatibility of certain materials in the
21 body?

22 A I performed my research in the form that
23 we discussed, that it's -- it's clinically -- I'm
24 taking care of patients every day.

1 So...

2 Q Okay. How about a synthetic foreign
3 body, like a -- like the TVT product compared to a
4 non-mesh product, is there anything unique that the
5 TVT product presents as a risk of dyspareunia?

6 A I think it would be generally the same
7 type of risk. Again, if you're -- even if you're
8 going to have an autologous, you know, it's still --
9 the body is going to have a reaction to placement of
10 something in there. So I don't think so, no.

11 Q The next sentence is: "When pelvic pain,
12 vaginal pain, or dyspareunia occur following a TVT
13 surgery, it is not the result of an alleged defect in
14 the TVT device or any inherent characteristic of the
15 device."

16 Did I read that correctly?

17 A You did.

18 Q Okay. So I see that broken down to two
19 parts. That it's not the result of, A, alleged
20 defect in the TVT device or, B, any inherent
21 characteristic of the device.

22 Do I -- do I interpret that correctly?

23 A I think that is a fair interpretation.

24 Q Okay. So breaking it down like that, one

1 could read this as when pelvic pain, vaginal pain, or
2 dyspareunia occur following a TVT surgery, it is not
3 the result of any inherent characteristic of the
4 device.

5 A I think that's a fair statement.

6 Q Okay. Doctor, is it your opinion that a
7 TVT mesh implant -- that when pelvic pain, vaginal
8 pain or dyspareunia occur after a TVT implant, it has
9 nothing to do with any inherent characteristics of
10 that TVT device?

11 A I think that's what I wrote.

12 Q So the fact that there's a synthetic
13 piece of mesh, piece of polypropylene implanted in
14 the body, there's nothing -- no inherent
15 characteristics of that that present a risk of
16 dyspareunia?

17 A I -- I don't think so. I mean, I -- the
18 poly -- the Prolene mesh that's used in the TVT
19 device has been in use for 40, 50 years. I've got a
20 couple of big pieces in my inguinal hernia here that
21 are -- well, the first one didn't work great. After
22 20 years I had to have another piece put in. So not
23 that that's caused dyspareunia up here, but, you
24 know, what -- again, I just don't see that there is

1 any reaction there.

2 Yes, dyspareunia happens after surgery,
3 no matter what it is.

4 But I think, to answer your question, I
5 don't think there's any inherent characteristic of
6 the device that would cause the dyspareunia.

7 Q So, Doctor, is it your -- is it your
8 opinion that the risk of dyspareunia is the same
9 across all SUI surgeries, mesh or non-mesh?

10 A I don't know if it's the same. Actually,
11 it -- I think with some of the other procedures you
12 may have some increased risk.

13 But the -- the underlying statement there
14 is that pain is a risk of surgery, any vaginal
15 surgery, whether it be a sling or any other repair,
16 there is a risk of dyspareunia.

17 Q And there's no inherent -- there's no
18 inherent characteristic of the TVT device that would
19 cause pelvic pain.

20 A That is my opinion.

21 Q There is no inherent characteristic of
22 the TVT device that causes vaginal pain.

23 A That is my opinion.

24 Q There is no inherent characteristic of

1 the TVT device that causes dyspareunia.

2 A Did you just ask that question again?

3 Q Vaginal pain and then I went to
4 dyspareunia. Pelvic pain, vaginal pain, dyspareunia.

5 A Yes. That I --

6 Q I mean I'll ask it so it's clean.

7 And, Doctor, there's -- it's your opinion
8 that there's no inherent characteristics of the TVT
9 device that cause dyspareunia?

10 A That is true.

11 Q Any --

12 A That's my opinion.

13 Q Any pelvic pain that occurs following a
14 TVT implant has nothing to do with the TVT product
15 itself.

16 A Again, I think you can have pain develop
17 from any procedure that you have done in the vagina,
18 whether there's mesh used or not.

19 Q If there is a TVT product implanted, not
20 talking about other products, in an instance where a
21 woman has a TVT product implanted, it's your
22 testimony there is nothing about that product and no
23 case that the TVT product causes the pelvic pain?

24 A I don't think there's -- I'm going to

1 just stick to my statement here. I don't think
2 there's any inherent characteristic of the device
3 that would cause vaginal pain or dyspareunia.

4 Q Meaning that it's --

5 A Do you have anything specific you're
6 trying to ask about with inherent characteristics of
7 the device?

8 Q Well, just -- I want to make sure I'm --
9 I'm not misinterpreting "inherent characteristic."

10 I mean the -- the TVT device, there's
11 nothing about the TVT device, the actual mesh product
12 implanted, there's nothing about that that causes
13 pelvic pain.

14 A That I -- there's no inherent
15 characteristic that I know of that -- that is related
16 to that. So if there's something else that you're --
17 characteristic you're interested in asking about --

18 Q This is -- this is my -- this is my
19 chance to make sure I understand, and that the
20 country understands, your opinions that are in
21 your -- in your report.

22 Moving on to the next section, "Erosion
23 or Exposure." It's going to be a similar line of
24 questioning, Doctor.

1 The first sentence reads: "Mesh erosions
2 or exposures are not attributable to any alleged
3 defect in the TVT or any inherent characteristic in
4 the TVT device."

5 Did I read that correctly?

6 MR. KOOPMANN: Object to form.

7 MR. CLINTON: Did I not --

8 MR. KOOPMANN: You almost did.

9 MR. CLINTON: I will try it again.

10 BY MR. CLINTON:

11 Q "Mesh erosions or exposures are not
12 attributable to an alleged defect in the TVT or any
13 inherent characteristic in the TVT device."

14 Did I read that correctly?

15 A Yes.

16 Q Okay. Is it fair that this breaks down
17 the same way that the previous statement about pelvic
18 pain does, that it's not attributable to a defect or
19 any inherent characteristic of the device?

20 MR. KOOPMANN: Object to form.

21 Go ahead.

22 THE WITNESS: I would agree with that
23 statement. That's what it says.

24 BY MR. CLINTON:

1 Q Doctor, the TVT product can erode in the
2 body, right?

3 A We're going back to our two definitions
4 of "erosion" versus "exposure."

5 Q Yes, sir. And the TVT product can erode.
6 There can be an erosion.

7 A It's not that the TVT product erodes, but
8 erosion happens into -- usually erosion can occur
9 into a structure, a hollow structure such as the
10 bladder or urethra.

11 Q So the TV --

12 A So it wouldn't be the TVT. It's not
13 erosion. It's an erosion. Not that the TVT device
14 is -- is eroding.

15 Q Well, that's what --

16 A It's not -- it's not disintegrating.
17 It's kind of what you say, it erodes. That to me
18 means that you may be inferring that it's
19 disintegrating, and that's not the case.

20 Q This is why we went over vocabulary
21 earlier so that when I --

22 A All right. Sorry.

23 Q -- when I say "erosion" and you say
24 "erosion," we're on the same page.

1 A I'm sorry.

2 Q We agree that the TVT product can erode
3 into other areas of the body?

4 A Erosions can occur.

5 Q With the TV -- erosions can occur with
6 the TVT product, correct?

7 A That's true.

8 Q Okay. And exposures can occur with the
9 TVT product?

10 A That's true.

11 Q Why do erosions occur, Doctor?

12 Strike that.

13 Doctor, what are some causes of erosion?

14 A I think the most likely cause for
15 erosions is going to be based on placement of the
16 device, and is it placed too close to -- to the --
17 you know, to the inner part of the urethra or too
18 close to the bladder.

19 So you can often see this sometimes --

20 I've seen it -- I haven't seen it occur, but I've

21 actually -- in placing the TVT device, when you put

22 it in there, and I have had perforations of the

23 bladder that I've seen right away, and we replace it,

24 but sometimes you can put it so it's very superficial

1 under which the -- the mesh is exposed to in the body
2 with the sheath covering it are -- are very low
3 pressures, and they really shouldn't -- you know,
4 there's really no clinically significant fraying.

5 If you take a piece of -- I know, I've
6 taken these things apart. Yeah, you can pull them
7 apart and they look crappy, they look horrible. But
8 that's not how it is in the body.

9 Q What about degradation of the mesh
10 product, do you have any opinion as to whether it
11 does or does not degrade inside the body?

12 A I've seen some internal documents, and
13 the experts -- the plaintiffs' experts' opinions
14 about that and looked at that a little bit. And I
15 think there is some -- while there was an argument
16 made that there was some degradation happening, what
17 it really turned out to be is that there was just a
18 coating that looked like fraying, but when the
19 coat- -- when the coating was taken off, that the
20 polypropylene itself or the Prolene itself really had
21 not degraded. And so I don't think there's any
22 degradation that occurs.

23 Q You --

24 A I don't think this stuff disintegrates in

1 the body.

2 Q And if you think it doesn't disintegrate
3 or degrade in the body, then I assume your opinion is
4 also that degradation doesn't cause any complications
5 with the mesh.

6 A That is true.

7 Q Okay. But truly your opinion is that you
8 don't believe there's any degradation that occurs.

9 A I don't think there's any clinically
10 significant issues with degradation.

11 Q And instead, your opinion -- your belief
12 is that there's a -- a coating that forms on the
13 mesh.

14 A That is the data I've reviewed.

15 Q How much data did you review regarding
16 degradation?

17 A Quite a bit, actually. The report -- and
18 I can't cite them verbatim for you, but there was a
19 lot of -- I think I was provided with a lot of what
20 your experts -- what the plaintiffs' experts were
21 using in their arguments, and I looked at that data,
22 and I looked at what -- you know, some other
23 contrasting data to -- to counteract those arguments,
24 and it really appears that it doesn't degrade.

1 But let me just add, more importantly
2 clinically, what happens to my patients, what happens
3 to our patients that we take care of, I've been using
4 this stuff for 20 years for treating urinary
5 incontinence, and it just -- degradation is not a
6 problem. It's just not a clinical problem.

7 Q Before you began your work as an expert
8 witness in this litigation, Doctor, had you
9 researched degradation specifically?

10 A To the point, again, clinically, are my
11 patients having any problems. So that would be the
12 extent of my research with regard to degradation.

13 Q I'm looking generally for any problems
14 that any patients experienced with the product.

15 A This is my patients experience with,
16 patients experience in the literature, in studies, in
17 randomized trials, in meta-analyses, in systemic
18 reviews, is there anything in any of the literature
19 in my patients, my colleagues' patients, is there
20 anything that shows that degradation is a real
21 clinical issue, and the answer is no.

22 Q Prior to your work beginning in this
23 litigation, Doctor, had you ever wondered to
24 yourself, does the mesh -- does the TVT mesh degrade

1 inside the body?

2 A I hadn't ever worried about it because
3 it's Prolene suture, and my understanding that I was
4 taught as a resident was the Prolene suture is
5 permanent.

6 Q And is it --

7 A It's a permanent suture.

8 Q And is it your opinion that the TVT
9 product presents the same risks that a Prolene suture
10 would, in terms of infection?

11 A I'm not quite sure I understand your
12 question.

13 Q Do you believe that the -- that a Prolene
14 suture presents the same risk that the TVT product
15 does in terms of risk of infection?

16 A I think it would depend on where the
17 suture was or -- you know, so I'm not quite
18 comfortable --

19 Q Used in a surgery for SUI.

20 A Yeah, I'm --

21 Q Do you have any opinion as to that?

22 A No, I --

23 Q Do you have any opinion as to whether a
24 Prolene suture versus a TVT product presents a risk